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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/893,535	06/29/2001	Robert E. Arbogast	OHI 1717-008A	4457

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EXAMINER	
COBANOGLU, DILEK B	
ART UNIT	**PAPER NUMBER**
3626	

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/893,535	ARBOGAST ET AL.	
	Examiner	Art Unit	
	Dilek B. Cobanoglu	3626	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39,46-49,65-69 and 80-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-39,46-49,65-69 and 80-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01/02/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice To Applicant

1. This communication is in response to the amendment filed 04/13/2006. Claims 1-39, 46-49, 65-69, 80-82 continue pending. The Applicant had been withdrawn rest of the claims on 12/20/2005 as a result of Restriction/Election requirement from the Examiner.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 31-37, 39, 46-48, 65-67 and 82 are rejected under 35 U.S.C. 102(e) as being unpatentable by Clynch (U.S. Patent No. 6,463,351 B1).

A. Claim 31 has been amended now to recite "querying the digital repository for a subset of medical device components based on the at least one patient attribute, the subset of medical device components collectively forming a medical device meeting the need of the patient (Clynch; col.7, lines 22-44 and 61-65 and col. 4, lines 14-39)

B. Claims 32-37 and 39 have not been amended, and Applicant does not appear to argue the separate patentability of these claims. As such, claims 32-39 are

rejected for the same reasons given in the previous Office Action (page number 3-5), and incorporated herein.

C. Claim 46 has been amended now to recite "means for populating a digital repository with information corresponding to a plurality of individual medical device components" (Clynch; col.4, lines 49-53 and col.7, lines 61-63 and col. 4, lines 14-39); and "means for querying the digital repository for a subset of medical device components based on the at least one patient attribute, the subset of medical device components collectively forming a medical device meeting the need of the patient" (Clynch; col.7, lines 22-44 and 61-65 and col. 4, lines 14-39).

D. Claims 47-48 have not been amended, and Applicant does not appear to argue the separate patentability of these claims. As such, claims 47-48 are rejected for the same reasons given in the previous Office Action (page number 13-14), and incorporated herein.

E. Claim 65 has been amended now to recite "populating a digital repository with information corresponding to a plurality individual medical device components" (Clynch; col.4, lines 49-53 and col.7, lines 61-63 and col. 4, lines 14-39); and "querying the digital repository for a subset of medical device components based on the at least one patient attribute, the subset of medical device components collectively forming a medical device meeting the need of the patient" (Clynch; col.7, lines 22-44 and 61-65 and col. 4, lines 14-39);

F. Claim 66 has not been amended, and Applicant does not appear to argue the separate patentability of this claim. As such, claim 66 is rejected for the same reasons given in the previous Office Action (page number 7), and incorporated herein.

G. Claim 67 has been amended now to recite "the method of claim 65, wherein the patient historical information comprises at least one of reimbursement information and L code information. "Claim 67 is rejected for the same reasons given in the previous Office Action (page number 7), and incorporated herein.

H. Claim 82 has not been amended, and Applicant does not appear to argue the separate patentability of this claim. As such, claim 82 is rejected for the same reasons given in the previous Office Action (page numbers 7-8), and incorporated herein.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-5, 8-14, 16, 19, 20, 22-30 and 80-81are rejected under 35 U.S.C. 103(a) as being unpatentable over Clynch (U.S. Patent No. 6,463,351 B1) in view of DeBusk et al. (U.S. Patent No. 6,581,204 B1).

A. Claim 1 has been amended now to recite "a digital repository populated with entries defining a plurality of medical device components, each entry associated with an individual medical device component (Clynch; col. 4, lines 14-39, lines 49-53 and col. 7, line 61 to col. 8, line 10); and "configurator mechanism configured to select a subset of entries from the digital repository based on the at least one patient interview answer indicator in the memory, the subset of entries including entries corresponding to individual medical device components that collectively form a medical device meeting a need of the patient (Clynch; col.7 ,lines 22-44 and 61-65).

B. Claims 2-5, 8-14, 16, 19, 20, 22-27, 29-30 and 80-81 have not been amended, and Applicant does not appear to argue the separate patentability of these claims. As such, claims 2-5, 8-14, 16, 19, 20, 22-27, 29-30 and 80-81 are rejected for the same reasons given in the previous Office Action (page number 10-18), and incorporated herein.

C. Claim 28 has been amended now to recite "a medical device component shopping mechanism is configured to place an order for a medical device component corresponding to at least one selected entry of the subset of entries and to store order information in the digital repository. (Clynch; col.5, line 53 to col. 6, line 17)

6. Claims 38, 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clynch (U.S. Patent No. 6,463,351 B1) in view of Vanker et al. (U.S. Patent Publication No. 2002/0099631 A1).

A. Claim 38 and 49 have not been amended, and Applicant does not appear to argue the separate patentability of this claim. As such, claim 38 and 49 have rejected for the same reasons given in the previous Office Action (page number 18-19), and incorporated herein.

7. Claims 68, 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clynch (U.S. Patent No. 6,463,351 B1) in view of Haller et al. (U.S. Patent Publication No. 2001/0051787 A1).

B. Claims 68 and 69 have not been amended, and Applicant does not appear to argue the separate patentability of this claim. As such, claim 68 and 69 have rejected for the same reasons given in the previous Office Action (page number 19-22), and incorporated herein.

8. Claims 6, 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clynch (U.S. Patent No. 6,463,351 B1) and DeBusk et al. (U.S. Patent No. 6,581,204 B1) as described above for rejection of claim 1, in further view of Vanker et al. (U.S. Patent Publication No. 2002/0099631 A1).

A. Claims 6 and 7 have not been amended, and Applicant does not appear to argue the separate patentability of this claim. As such, claims 6 and 7 have rejected for the same reasons given in the previous Office Action (page number 22-23), and incorporated herein.

9. Claims 15, 17, 18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clynch (U.S. Patent No. 6,463,351 B1) and DeBusk et al. (U.S.

Patent No. 6,581,204 B1) as described above for rejection of claim 1, in further view of Haller et al. (U.S. Patent Publication No. 2002/0099631 A1).

A. Claims 15, 17, 18 and 21 have not been amended, and Applicant does not appear to argue the separate patentability of this claim. As such, claims 15, 17, 18 and 21 have rejected for the same reasons given in the previous Office Action (page number 23-25), and incorporated herein.

Response to Arguments

10. Applicant's arguments filed 04/13/2006 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 04/13/2006.

11. At page 25, the Applicant argues that Clynch reference does not mention about a digital repository or any medical device components. In response, the Examiner respectfully submits that Clynch reference teaches a digital database of medical components or devices derived based on prior successful medical devices, which is a repository (col. 7, line 61-65 and Fig 3), also default options of any body portion such as back, shoulder, torso, arm, hand, neck or head as described on col. 7, lines 24-32 describe a medical components repository.

12. At page 25, the Applicant argues that Clynch reference does not mention about medical components, and the cited section of col. 7, lines 14-52 does not recite medical components. In response, the Examiner respectfully submits that Clynch reference teaches medical components such as patellar tenon bar or head of fibula or posterior wall extention. The Clynch reference also continues on col. 4, lines 14-39 that the

medical components could be braces/supports of for weak or ineffective joints or muscles and custom seats for wheelchairs. Examiner believes that these are medical components.

13. At page 25-26, the Applicant argues that Clynch reference does not mention about interviewing a patient having a need for a medical device to determine at least one patient attribute. In response, the Examiner respectfully submits that Clynch reference teaches patient visiting a physician's office on col. 5, lines 1-4 and Clynch reference continues on col. 5, lines 36-41 that during the modification of site marking process a tubular modeling is used for a prosthetic leg example. Examiner believes that it is very obvious that the physician or nurse would ask the patient if he/she feels comfortable or if the weight of the tubular modeling material is comfortable enough for the patient's needs, such as his/her lifestyle. Also, the Clynch reference mentions on col. 5, lines 36-41 that the patient is permitted to load the tubular modeling material with a certain body weight during the modification site marking process. Examiner believes that the desired weight of the material is of the attributes of the patient and one of the options that patient could select as an attribute.

14. At page 26, the Applicant argues that Clynch reference does not mention about storing at least one such patient attributes. In response, the Examiner respectfully submits that Clynch reference states on col. 5, lines 53-59 that the scanning process creates a scan data file such as image data file is downloaded to the physician's clinic to permit the physician, who is most familiar with the requirements for the medical device. Examiner believes that this action is storing the patient's attribute, because the

physician would know the requirements of the patients and can modify the medical device accordingly and he does this his computer. It is very obvious that the physician would store this information as well.

15. At pages 26-27, the Applicant argues that the operation of CAD application as disclosed by Clynch reference is not the same as querying for or selecting medical device components. In response, the Examiner respectfully submits that Clynch reference teaches on col. 5, lines 1-4 that the process of constructing a medical device begins in a physician's office, where a modeling material is fitted to the body part of a patient requiring a medical device and also on lines 27-41 it teaches an example of using a tubular modeling material. It is very obvious that the physician would ask the patient if she/he feels comfortable with the model.

16. At page 27, the Applicant argues that Clynch reference mentions about single component medical device, whereas the application is directed to a complex medical devices. In response, the Examiner respectfully submits that Clynch reference teaches on col. 4, lines 14-39 that the invention can be used to produce custom designed medical devices or components such as artificial limbs, braces, plastic surgery implants and even custom seats for wheelchairs. Examiner believes that these are complex components.

17. At page 28, the Applicant argues that Clynch and DeBusk references do not mention about a digital repository. In response, the Examiner respectfully submits that this argument has been addressed above in paragraphs 11, and incorporated herein.

18. At page 28, the Applicant argues that Clynch and DeBusk references do not mention about at least one patient attribute. In response, the Examiner respectfully submits that this argument has been addressed above in paragraphs 13, and incorporated herein.

19. At page 29, the Applicant argues that Clynch and DeBusk references do not mention about a practitioner user interface mechanism configured to provide a practitioner with access to entries in the digital repository via a network and to allow the practitioner to provide at least one patient interview answer indicator. In response, the Examiner respectfully submits that Clynch reference teaches on col. 7, lines 24-32 that default options in a pull down menu and continues on lines 45-52 discloses some of the options. And on lines 61-65, Clynch reference continues to teach that the default modifications are derived from prior successful medical devices. As described before that the Clynch reference teaches that the physician modifies the model image to customize according to the patient's specific needs.

20. At page 29, the Applicant argues that Clynch and DeBusk references do not mention about patient interview mechanism. In response, the Examiner respectfully submits that this argument has been addressed above in paragraphs 13, and incorporated herein.

21. At page 29, the Applicant argues that Clynch and DeBusk references do not mention about configurator mechanism configured to select a subset of entries from the digital repository based on the at least one patient interview answer indicator in the memory, the subset of entries including entries corresponding to individual medical

device components of a medical device meeting a need of the patient. In response, the Examiner respectfully submits that Clynch reference teaches on col.7, lines 22-44 and 61-65 that the pull down menu includes the default options and they are prior successful medical devices, also on col. 5, lines 53-59 Clynch reference teaches that the physician modifies the scanned image which is stored. Examiner also would like to emphasize that the physician is most familiar with the requirements for the medical device because especially described on col. 5, lines 1-4 and lines 36-41 that the physician examines the patient for the specific needs. Examiner believes that it is very obvious that the physician would ask questions at the examination and store and use the answers to modify the scanned image for the patient.

Conclusion

22. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

23. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dilek B. Cobanoglu whose telephone number is 571-272-8295. The examiner can normally be reached on 8-4:30.

25. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

26. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 3626
06/21/2006

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